

the polypeptide essentially free of intracellular immunoreceptor tyrosine-based inhibition motifs and having a molecular weight of between about 25 kilodaltons and about 65 kilodaltons.

7. (Amended) A composition comprising the polypeptide of claim 6 and a pharmaceutically acceptable carrier.

### **REMARKS**

This amendment is in response to the Office Action dated May 6, 2002. Claims 1-12 were examined in the Office Action. Applicants respectfully request reconsideration of the outstanding rejections for the reasons that follow.

Applicants have amended claim 1. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. Applicants submit the amended claims do not raise any issues of new matter. The attached page is captioned "Version with markings to show changes made."

#### **A. Objection To Disclosure Addressed**

The disclosure was objected to as containing an embedded hyperlink. Applicant has amended the disclosure to remove the problematic language. As such, Applicants respectfully request withdrawal of the objection to the disclosure on this basis.

#### **B. Objection to Drawings Addressed**

The drawings, Figures 1-4, are objected to as containing various defects. In particular, Figures 3 and 4 were objected to as having erasures, alterations, overwritings, etc, Figures 2 and 3 were objected to as having unacceptable margins, and Figures 1 and 2 for having non-legible reference characters and reference characters under the 0.32 cm height requirement. Applicant notes that formal drawings, in abeyance with the draftperson's notice, will be submitted within the three-month shortened statutory period set upon any one of the pending claims allowance.

**C. Rejection under 35 U.S.C. § 101 Addressed**

Claims 1-12 were rejected under 35 U.S.C. § 101. The Examiner contends that the claimed invention is not supported by either a specific and substantial utility or a well-established utility. This rejection is respectfully traversed for claims 1-12.

The Examiner's attention is respectfully drawn to M.P.E.P § 2107.01 under the section entitled "Specific Utility." This section states in part: "... A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial and credible by a person of ordinary skill in the art in view of all the evidence of record."

As disclosed in several of the incorporated references on page 16, C-lectin superfamily receptors have been shown to be approximately 200 to 280 amino acids in length, and express C-terminal CRDs, type II transmembrane domains, and N-terminal cytoplasmic tails. Typically members of this family of receptors are expressed in NK cells, but expression is not restricted to these cells. Members of the family are mapped to a highly conserved area of chromosome 12, termed the NKC-linked genes. Function of this receptor superfamily are associated with the activity of NK and other immune function cells, and in particular, CD69 has been shown to activate cell-specific functions of lymphocytes, granulocytes, monocytes and platelets. The utility of this family of receptors is well supported within the incorporated references.

The putative sequence of LLT1 discloses each of the C-lectin superfamily conserved motifs (see Figures 1 and 2), including a transmembrane domain, intracellular domain and extracellular lectin-like domain having two N-linked glycosylation sites. The data in the present case also shows that the disclosed sequenced of LLT1 has strong homology to CD69 and AICL, two members of the C-type lectin superfamily. Data in Examples 3 – 5 indicate that the expression of LLT1 corresponds to NK cells, as would be expected of a member of the C-lectin superfamily of receptors, and is localized in the NK gene complex of chromosome 12. In particular, LLT1 is shown to be within 100 kb of the CD69 gene. This data supports a conclusion that LLT1 is a member of the C-lectin superfamily of receptors, having a utility in the activation of lymphoid tissue, much like CD69. The utility of the claimed LLT1 is specific, substantial and credible, especially as viewed by a person of ordinary skill in the art, in view of

all the evidence of record. The utility of the present invention is supported by further research, as disclosed in a continuation-in-part application as filed on this day. The data supports a finding that LLT1 is a member of the C-lectin superfamily of receptors, involved in the activation of NK cells.

**D. Rejection under 35 U.S.C. § 112, First Paragraph Addressed**

The Examiner rejected claims 1-12 under § 112, first paragraph because the Examiner contends that the specification is not reasonably enabled with regard to providing sufficient information or working examples on how to produce and use the variants of claimed receptor of SEQ ID NO:2. Applicants respectfully traverse the rejection to this rejection.

The basic inquiry into whether a particular claim is supported by the disclosure is whether “one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” See MPEP 2164.01 citing United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988).

Amended claim 1 and dependent claims thereof, recite a LLT1 receptor. Applicants have provided in Figure 1 the sequence of LLT1, thereby satisfying the first inquiry under the USPTO Enablement Guidelines, that the specification teach how to make and use at least one embodiment of the claims without undue experimentation.

The second inquiry, “Are the enabled embodiments representative of the full scope of the claims?” is at issue. The Guidelines particularly note “If specific technical reasons cannot be given or properly supported with sufficient evidence, then the answer to the previous question should have been yes.” (Enablement Decision Tree, USPTO Training Manual, 35 USC 112, First Paragraph, Enablement). Further, the scope of the enablement must only bear a “reasonable correlation” to the claims.”

Applicants have shown the sequence shown in Figures 1 and comparison of that sequence to other C-type lectin superfamily receptors (Figure 2). Further, Examples 1-6 walk through the procedure for cloning and characterizing the LLT1 receptor, indicating the importance and function of particular amino acid motifs. Applicants disagree with the Examiner’s characterization that the claimed polypeptides are not predictable. Based on the teachings of the

specification, it is reasonable to conclude that the claims are properly supported with sufficient evidence and that the scope of the enablement bears a reasonable correlation to the scope of the claims.

Applicants further contend that when one considers other factors, for example, breadth of claims, nature of the invention, state of the prior art, level of ordinary skill in the art, level of predictability in the art and the amount of direction, including working examples, provided by the invention (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)), that one of skill in the art would be able to practice the invention. In looking to the Applicants' specification, Applicants have provided information about the structure of the LLT1 receptor and motifs of the LLT1 receptor; parameters used to identify the similarity of the LLT1 receptor to other C-type lectin members; working examples on the characterization of the LLT1 receptor; and that the level of skill in the art is high. Accordingly, it is respectfully requested that the § 112, first paragraph rejection be withdrawn.

**E. Rejection under 35 U.S.C. § 112, Second Paragraph Addressed**

Claims 1 and 7-10 were rejected under 35 U.S.C. § 112, second paragraph. The Examiner contends that it is indefinite in claim 1 to use the acronym "ITIM" in a claim limitation, or to direct a claim to both a polypeptide and a pharmaceutical composition comprising the polypeptide. The problematic language has been corrected in claims 1 and 7 thereby overcoming the § 112, second paragraph rejection. Therefore, Applicants respectfully request withdrawal of the rejection.

**F. Rejection Under § 102 Addressed – Boles et al**

Claims 1-12 are rejected under 35 U.S.C. § 102 as anticipated by Boles et al.

The rejection is respectfully traversed with respect to amended claims 1-12. It is respectfully noted that the present case has a priority date of December 30, 1999, and it is therefore believed that the Boles et al. (Immunogenetics 50:1-7, 1999) is not proper § 102(b) art. As such, Applicants respectfully request withdrawal of the rejection to claims 1-12 on this basis.

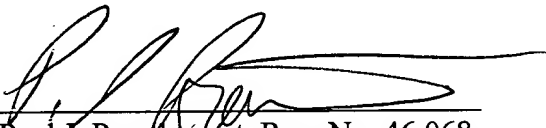
**G. Summary**

Claims 1-12 remain pending. In light of the foregoing amendments and remarks, it is believed that the application is in condition for allowance, prompt allowance is respectfully solicited.

This amendment is believed to be responsive to all points in the Office Action and is believed to put the case in condition for allowance. Should the Examiner have any remaining questions, she is encouraged to contact the undersigned attorney at the telephone number below to expeditiously resolve such concerns.

Please charge any additional fees or credit any overpayment to Deposit Account No. 04-1415.

November 6, 2002

  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

The sentence on page 7, line 21 has been amended as follows:

In the Specification

The expressed sequence tag (EST) database at GenBank [(http://www.ncbi.nlm.nih.gov)] was searched with the TblastN program against [vs.] a consensus sequence of human (CD69, CD94, and NKG2's) and mouse (Ly-49's) C-type lectin receptors (Boguski et al. 1993, 1995).

In the Claims

1. (Amended) A polypeptide [comprising a] molecule having an amino acid sequence derived from a lectin-like transcript 1 receptor wherein the receptor has a transmembrane domain near the N-terminus of the polypeptide, and having a length of about 185 to about 205 amino acid residues [wherein said], the polypeptide essentially free of intracellular [ITIM] immunoreceptor tyrosine-based inhibition motifs [, wherein said] and having a molecular weight of between about 25 kilodaltons and about 65 kilodaltons.
  
7. (Amended) [The] A composition comprising the polypeptide of claim 6 [wherein said polypeptide is further defined as] and a pharmaceutically acceptable [preparation] carrier.